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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,013	04/24/2000	HIROYUKI SHIMIZU	32-254P	7526

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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 02/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/530,013

Applicant(s)

Shimizu et al.

Examiner

Ralph Gitomer

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 4, 2002
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

The amendment received 9/4/2002 has been entered and claims 1-6 are currently pending in this application.

5 Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10 The claims have been amended to include the limitation of excluding the addition of any degradation-inhibiting agents which is new matter. A negative limitation requires the highest degree of written description and no written description is found for the new limitation.

15 Applicant's arguments filed 9/4/2002 have been fully considered but they are not persuasive.

 Applicants argue that the specification provides written description for the negative limitation in three places.

20 1. Page 2, lines 4-6:

The addition of degradation inhibiting agents, e.g., aprotinin etc. ... had been essential.

2. Page 3, lines 6-9: Therefore, it is expected that the former complicated handling of specimens can be eliminated by using a container wherein the face coming into contact with specimens is made of materials other than glass...

3. Page 4, lines 18-19: This invention relates to a measurement of natriuretic peptide in specimens which do not contain aprotinin.

It is the examiners position that none of the above citations provide any written description directed to excluding anything added to the assay.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant

is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Lindberg in view of Clerico.

Lindberg (Pharmacology & Tox) entitled ~~¶~~Adsorption of Atrial Natriuretic Peptide to Different Materials~~¶~~ teaches on page 278 column 2 first paragraph, loss of recovery of ANP at different concentrations in different containers was determined where the containers include siliconized glass and coated polymers.

The claims differ from Lindberg in that they are directed to a method for inhibiting degradation of the peptides and Lindberg is directed not to storage but to contacting containers only as related to concentration.

Clerico (Clin Chem) entitled ~~¶~~Analytical Performance and Clinical Usefulness of a Commercially Available IRMA Kit for Measuring Atrial Natriuretic Peptide in Patients With Heart Failure~~¶~~ teaches on page 1631 column 2 last paragraph, storage of ANP degrades it.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the containers of Lindberg which show the greatest recovery of ANP to store ANP

containing specimens as shown by Clerico because Clerico teaches storing ANP in general degrades it. It would appear from Lindberg the silicone coated containers do not degrade ANP as much as others and would therefor desirable for storage of ANP which is known to be sensitive to degradation in storage.

Applicant's arguments filed 9/4/02 have been fully considered but they are not persuasive.

Applicants argue that Lindberg and Clerico do not disclose a method for inhibiting the activation of a substance degrading natriuretic peptides using specialized containers. There is no motivation to combine the references. And the references require degradation inhibiting agents such as aprotinin or HAS.

It is the examiner's position that both Lindberg and Clerico employ containers for holding ANP that are made of the same materials disclosed in the present specification. They would not use containers that would not work, and they show that the containers that they do use, do work. Regarding the addition of degradation inhibiting agents, on page 4 fifth paragraph of the present specification, aprotinin is known to be added to specimens to inhibit degradation of the peptides. The examples in the specification do not teach the specific addition of such inhibitors but compare the materials of the storage container. This is logical in that the fewer factors measured would lead to the most valuable result. However, it would appear the addition

of aprotinin, as is current standard practice, would indeed inhibit the degradation as the claims are drawn to. The addition of known inhibitors would have the expected result and conversely, the lack of addition of the inhibitors would have the expected result as well. No invention is seen in not adding the known inhibitors. Importantly, no amount of inhibiting is claimed and the claims as presented are written in open-ended ~~comprising~~ terminology which does not exclude additional steps or reagents.

The motivation to modify a reference can come from the knowledge of those skilled in the art, from the prior art reference itself, or from the nature of the problem to be solved. See *In re Rouffet*, 149 F.3d 1350, 1358, 47 USPQ2D (BNA) 1453, 1458 (Fed Cir. 1998)

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing

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date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

5 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If

10 attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for this Art Unit is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist
15 whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button Patent Electronic Business Center for more information.

20 *Ralph Gitomer*
Ralph Gitomer
Primary Examiner
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25 RALPH GITOMER
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